

510(k) Summary of Safety and Effectiveness**Name, Address and Establishment Registration No.**

The address and registration number of the manufacturer is as follows:

Hand Innovations, LLC
 8905 SW 87 Avenue, Suite 220
 Miami, FL 33176-2227
 Establishment Registration No.: 9042874
 Tel.: (305) 270-6899
 Fax: (305) 412-8060

ATE 28 2005

General Provisions

The name of the device is:

Proprietary Name	Common or Usual Name
Multidirectional Threaded Peg	Plate Fixation Bone

Name of Predicate Devices

The device is substantially equivalent to:

- Threaded Peg of the Distal Volar Radius Anatomical Plate System (510(k) # K050932 – April 26, 2005) – Hand Innovations, LLC.

Classification

Class II.

Performance Standards

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

Indications for Use

The Multidirectional Threaded Pegs have the same indications for use as the predicate device:

The Distal Volar Radius Anatomical Plate System is intended for the fixation of fractures and osteotomies involving the distal radius.

Device Description

The proposed **Multidirectional Threaded Peg** is manufactured from Cobalt Chromium (CoCr) and is available in 2.5 mm diameter and in a variety of lengths, ranging from 10 – 30 mm in 2 mm increments to accommodate varying patient anatomies and fracture morphologies.

Biocompatibility

The Proposed **Multidirectional Threaded Peg** do not require biocompatibility testing because the CoCr Alloy used in the fabrication meets the requirements of ASTM F 1537-00.

Summary of Substantial Equivalence

The proposed **Multidirectional Threaded Peg** is substantially equivalent to the predicate threaded peg of the Distal Volar Radius Anatomical Plate System. The equivalence was confirmed through pre-clinical testing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 2006

Hand Innovations
c/o Ms. Natalie S. Heck
Manager, Regulatory Affairs
DePuy Orthopaedics, Inc.
8905 SW 87th Avenue, Suite 220
Miami, Florida 33176

Re: K060864

Trade/Device Name: Multidirectional Threaded Peg

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: II

Product Codes: LXT

Dated: April 24, 2006

Received: April 26, 2006

Dear Ms. Heck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

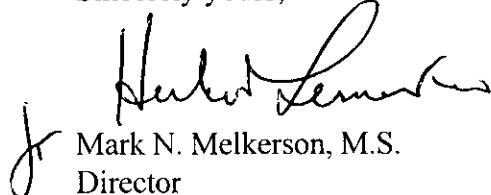
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson, M.S.
Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K060864

Device Name: **Multidirectional Threaded Peg**

Indications for Use Statement

The Distal Volar Radius Anatomical Plate System is intended for the fixation of fractures and osteotomies involving the distal radius.

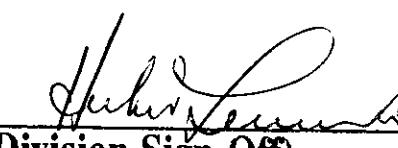
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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

OR

Over-The-Counter Use _____


Julie L. Lembke
(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

510(k) Number K060864